REMARKS

The Rejection of Claim 53 under 35 U.S.C. §112, Second Paragraph

The improper dependency has been corrected by this Amendment.

The Rejection of Claims 2, 4, 8, 20-22, and 33 Under 35 U.S.C. § 103(a)

Claims 2, 4, 8, 20-22, and 33 have been rejected under 35 U.S.C. § 103(a) as unpatentable over Steinman (U.S. 5,516,292) in view of Stratagene Catalog 1995. Applicants respectfully traverse the rejection.

Steinman is cited for teaching use of a restriction endonuclease – not *Alu*I– for decontaminating a PCR reaction. Stratagene is cited to teach that *Alu*I is a known restriction endonuclease. The Office Action asserts that it would have been obvious to combine the two teachings and that one of skill in the art would have had a reasonable expectation of success.

However, as evidence already of record demonstrates, one of skill in the art would not have had a reasonable expectation of success. The evidence of record indicates that one of skill in the art would have had an expectation of failure for its intended purpose. DeFelippes, previously cited in a prior Office Action, attempted to use *Alu*I to decontaminate *in vitro* amplification reagents. However, DeFelippes taught that *Alu*I was not suitable for the intended purpose.

DeFelippes tested *Alu*I for its ability to successfully decontaminate *in vitro* amplification reagents. However, DeFelippes found that *Alu*I was not suitable for this purpose. DeFelippes found that "digestion with *Alu*I, illustrated in Figure 1, **was not routinely successful**, and in some cases a light band was present at the proper position in lane 7 although no template was added after the inactivation of the *Alu*I." Page 28, sentence spanning columns 2 and 3. Using

the same test template but a smaller amplification target, DeFelippes reported, "In this case also, *Alu*I **did not always completely inactivate** the template." Page 28, column 3, lines 9-11.

When DeFilippes is considered as a whole, DeFilippes teaches away from the use of *Alu*I in such an *in vitro* amplification method because DeFilippes teaches that AluI does not effectively digest *in vitro* amplification reagent mixtures, *i.e.*, *Alu*I does not effectively eliminate contaminating DNA that is present in reagents for *in vitro* amplification. DeFilippes teaches that in both a first and a second set of test assays, *Alu*I did not successfully decontaminate the reagents for *in vitro* amplification.

Moreover, further evidence already of record in Exhibits A-J of the June 13, 2006 Amendment demonstrates that anything less than complete decontamination is not suitable for the intended use of diagnostic PCR amplification.

The Patent Office has agreed that DeFelippes teaches away, withdrawing the rejections citing DeFelippes. "With regard to the rejection made in the previous office action under 35 U.S.C. §103(a) as being unpatentable over Steinman et al., in view of DeFelippes, Applicants' arguments are fully considered and the rejection is withdrawn in view of the persuasive arguments and new grounds of rejections." Office Action mailed September 22, 2006, at page 7, lines 16-19. Whether DeFelippes is cited in a rejection or not, its teaching remains in the prior art and remains relevant to the assessment of non-obviousness. "A prior art reference that 'teaches away' from the claimed invention is a significant factor to be considered in determining obviousness…." M.P.E.P. 2145(X)(D)(1). "A prior art reference must be considered in it entirety, i.e., as a whole, including portions that would lead away from the claimed invention. M.P.E.P. 2141.02(VI). A reference may be said to teach away when a person of ordinary skill,

upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant…in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the Applicant." *In re Gurley*, 27 F3d 551, 553 (Fed. Cir. 1994). See also, *In re Caldwell*, 319 F2d 254, 256 (C.C.P.A. 1963) (reference teaches away if it leaves the impression that the product would not have the property sought by the applicant.)

As previously demonstrated by Exhibits A-J, PCR decontamination must be complete or the desired analysis will be inaccurate and unreliable. Therefore, a person of skill in the art would not have combined the two reference teachings of Steinman and Stratagene because DeFelippes taught away from the success of the result.

Withdrawal of this rejection is therefore respectfully requested.

The Rejection of Claims 5-7 and 9-19 Under 35 U.S.C. §103(a)

Claims 5-7 and 9-19 are rejected as obvious over Steinman and Stratagene, cited and discussed above, further in view of Hoshina.

Each of the rejected claims is dependent on claim 2. Hoshina is cited to teach various additional limitations of the dependent claims. For example, a treated blood sample, systemic bacteremia, a particular single primer, gel electrophoresis, ethidium bromide, urine, cerebrospinal fluid, 16S RNA, sequencing, and restriction mapping are all allegedly taught by Hoshina. However, Hoshina does not cure the deficiency of the two primary references or overcome the teaching away of the record evidence.

DeFelippes and Exhibits A-J submitted June 13, 2006, establish persuasively and definitively that there would have been no reasonable expectation of success for the method of the present invention because DeFelippes taught the unsuitability of *Alu*I for PCR reagent decontamination. Thus, the *prima facie* case of obviousness is rebutted and overcome by the record evidence.

Withdrawal of this rejection is respectfully requested.

Respectfully submitted,

By: /Sarah A. Kagan/
Sarah A. Kagan
Registration No. 31,141

Date: December 22, 2006

Customer No. 22907
Banner & Witcoff, LTD.